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10/579,770	03/12/2007	Viggo Aaberg Kaern	2003039-US	5690
69289	7590	02/08/2010	EXAMINER	
COLOPLAST A/S			TREYGER, ILYA Y	
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Holtedam 1			ART UNIT	
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			NOTIFICATION DATE	
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			02/08/2010	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@coloplast.com  
dkbvd@coloplast.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,770	<b>Applicant(s)</b> KAERN ET AL.	
	<b>Examiner</b> ILYA Y. TREYGER	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 20-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

- I. Claims 1-12, drawn to a device for providing anti-reflux, classified in class 604, subclass 323.
- II. Claim 14-19, drawn to a method of manufacturing a valve element, classified in class 137, subclass 855.

The inventions are distinct, each from the other because of the following reasons:

- 1. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed process can be used to make a valve element that does not require a valve seat.
- 2. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

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(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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3. During a telephone conversation with Mr. Bumann on 01/28/2010 a provisional election was made without traverse to prosecute the invention of a device for providing anti-reflux, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Claims 13 and 20-22 are canceled.

6. Claims 14-19 are withdrawn.

7. Claims 1-12 are examined on the merits.

### ***Response to Arguments***

Applicant's arguments with respect to claim 1-12 and 14-19 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

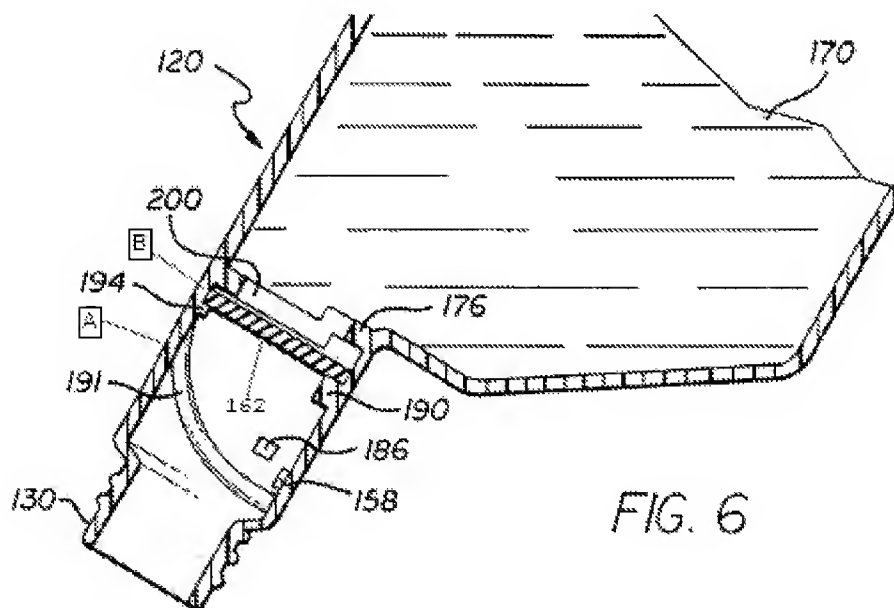
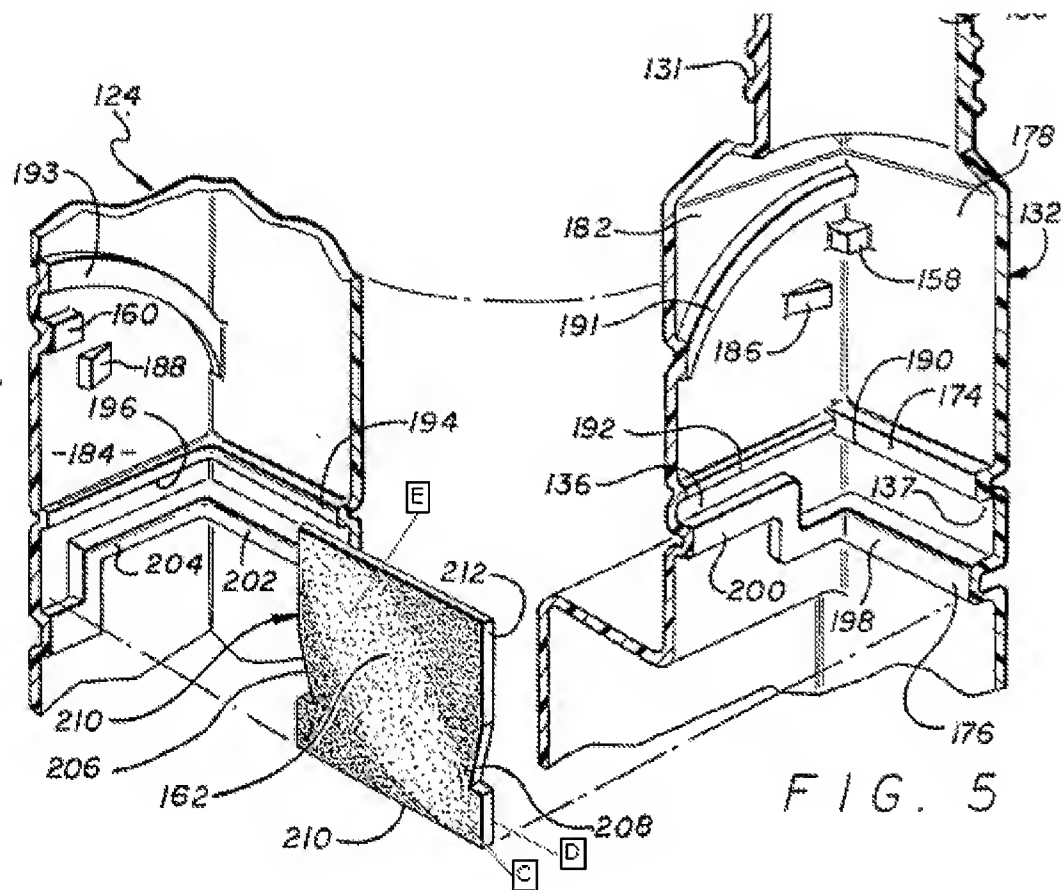
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9. Claims 1, 2, 6, 7, 9, 10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jangaard (US 5,472,123).

10. In Re claim 1, Jangaard discloses a neck of a bottle that is an anti-reflux device comprising:

a wall A (Fig. 6) providing a valve seat B (Fig. 6), and a valve element 162 (Figs. 5 and 6) defining an outer contour 212 (Fig. 5) formed from a sheet-shaped material, said valve element including a connecting portion C (Fig. 5) and a flap portion E (Fig. 5) defining a longitudinal direction extending between the connecting portion and the flap portion, and retaining means 190 (Fig. 6) fully capable of retaining the valve element 162 with respect to the device, said retaining means being integral with the device. The connecting portion C (Fig. 5) includes the engagement means D (Fig. 5) formed integrally with the valve element for engagement with the retaining means, wherein the valve element projecting a coherent plane (See Col. 8, lines 9-21 and 32-46; Figs. 5 and 6).

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11. In Re claims 2 and 10, Applicant sets forth the manner in which the claimed apparatus operates. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Since Jangaard discloses substantially the same structure, as that claimed by applicant, the structure is fully capable of performing the claimed function.

12. In Re claims 6, 7, and 9, Jangaard discloses a device in which said outer contour A forms a curve defining a continuously advancing function on a respective side of the longitudinal direction (claim 6), and wherein the engagement means D are formed within (claim 7) and integrally (claim 9) in said outer contour (claim 7) (See Fig. 5).

13. In Re claim 12, Jangaard discloses the valve element including at least one connecting portion and a flap portion and defining a longitudinal direction extending between the connecting portion and the flap portion, and with engagement means integrally formed in the valve element (See Col. 8, lines 9-21 and 32-46; Figs. 5 and 6).

With respect to limitation regarding that the valve element including the engagement means is manufactured by cutting along a closed line in a sheet-shaped material blank, claim 12 is a product-by-process claim, and since the claimed product is fully disclosed by the reference, the method of the manufacturing the engagement means imbedded in the claim does not impact patentability to the claim.

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

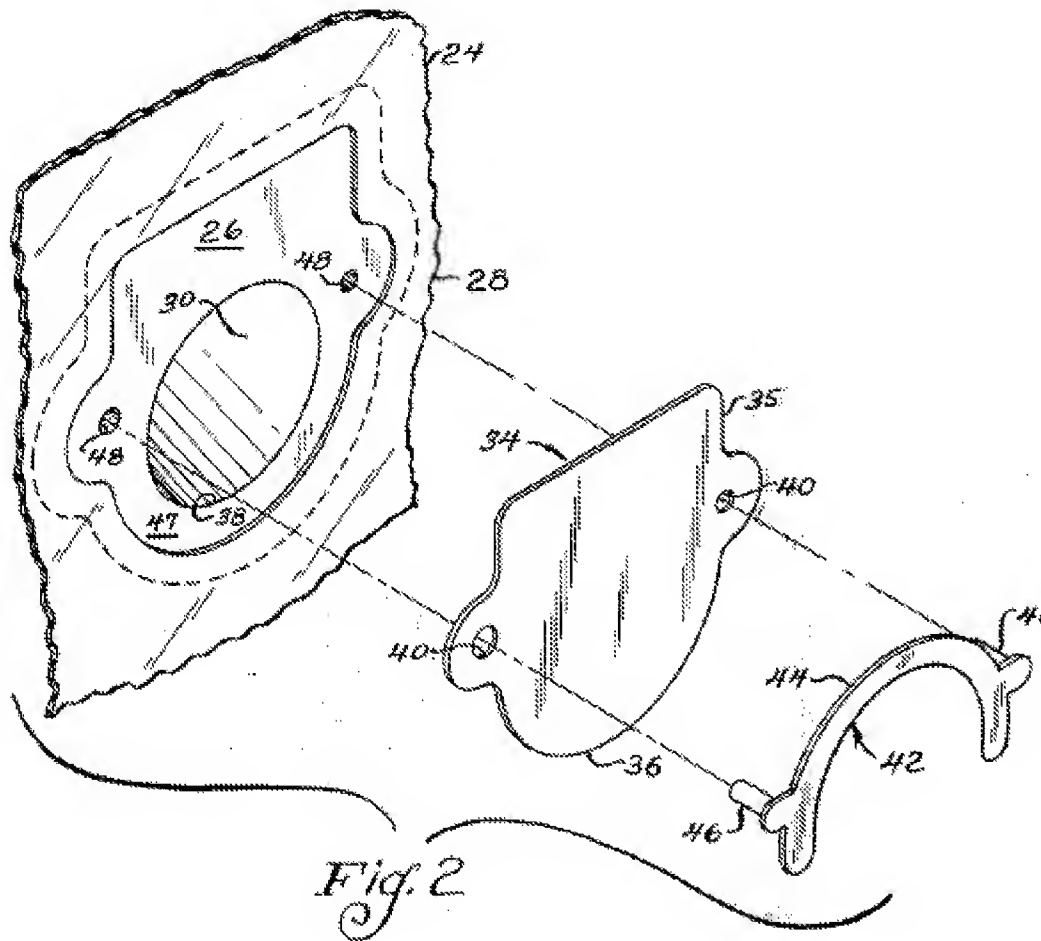
16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jangaard (US 5,472,123) in view of Boedecker (US 3,965,900).

Jangaard discloses the invention discussed above, as applied to claim 10, but does not expressly disclose the use of the device in the structure defining a catheter, a drainage tube connected to the catheter, and the connector to the collection bag.

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Boedecker teaches the use of the device substantially identical to that claimed by the Applicants in the structure defining a catheter, a drainage tube connected to the catheter, and the connector to the collection bag (Col. 2, lines 54-59; Fig. 2).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of Jangaard in the structure defining a catheter, a drainage tube connected to the catheter, and the connector to the collection bag, as taught by Boedecker in order to utilize the conventionally known application for the one-way anti-reflux flap valve.

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18. Claims 3, 4, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jangaard (US 5,472,123) in view of Morone (US 5,027,754).

Jangaard discloses the claimed invention discussed above, but does not expressly disclose the device, wherein the engagement means are slit-shaped (claim 8) or incision-shaped (claims 3 and 4).

Morone teaches the flap valve wherein the valve element is slit- or incision-shaped (since the incision is a variation of slit) (See Fig. 2).

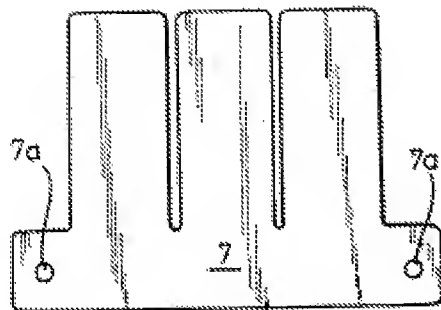


FIG.2

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the valve element of Jangaard slit- or incision-shaped, as taught by Morone in order to improve valve element fixation.

***Allowable Subject Matter***

19. Claim 5 is allowed.

20. The following is a statement of reasons for the indication of allowable subject matter:

The specific limitations of “a hook- shaped section” are not anticipated or made obvious by the prior art of record. For example, the US 3,965,900 teaches a valve element 34 (Fig. 2) defining an outer contour A (Fig. 2) formed from a sheet-shaped material, said valve element including a

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connection portion B (Fig. 2) and a flap portion C (Fig. 2) defining a longitudinal direction extending between the connecting portion and the flap portion, and bores 48 (Fig. 2) which are retaining means for retaining the valve element 34 with respect to the device, said retaining means being integral with the device.

US 5,027,754 teaches the flap valve wherein the valve element is slit- or incision-shaped (since the incision is a variation of slit) (See Fig. 2).

However US 3,965,900 and US 5,027,754 fail to teach or suggest the specific limitations of a hook- shaped section which improves the fixation of the device.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/  
Examiner, Art Unit 3761

*/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761*